IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

SALIX PHARMACEUTICALS, INC., SALIX PHARMACEUTICALS, LTD., ALFASIGMA S.P.A and BAUSCH HEALTH IRELAND, LTD.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Case No: 1:25-cv-24 Kleeh

[redacted]

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS COUNTERCLAIM III

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Pursuant to Fed. R. Civ. P. 12(b)(1), 12(b)(6), and 28 U.S.C. §2201, Plaintiffs Salix Pharmaceuticals, Inc., Salix Pharmaceuticals, Ltd., Bausch Health Ireland, Ltd., and Alfasigma S.p.A. (collectively, "Salix") move to dismiss Count III of Defendant Mylan Pharmaceuticals Inc.'s ("Mylan") Counterclaims. In Counterclaim III, Mylan seeks a declaratory judgment of non-infringement of U.S. Patent Nos. 8,969,398 ("'398 Patent"), 8,946,252 ("'252 Patent"), 8,829,017 ("'017 Patent") and 8,642,573 ("'573 Patent") (collectively, "HE Patents"). The Court should dismiss this counterclaim for lack of a justiciable controversy and lack of Article III standing. Alternatively, assuming an Article III controversy for the counterclaim exists and is sufficiently pleaded, the Court should exercise its discretion to dismiss Counterclaim III because it will likely become moot during this litigation, making the exercise of jurisdiction an inefficient use of judicial resources.

I. BACKGROUND

A. Xifaxan®

This patent infringement action arises from Mylan's submission of Abbreviated New Drug Application No. 219687, which seeks FDA approval to manufacture and sell a generic version of Salix's Xifaxan® (rifaximin tablets, 550 mg) product ("Xifaxan® 550 mg") before the expiration of certain patents covering rifaximin and methods of using rifaximin. Dkt. 1 ¶ 1.

Xifaxan® 550 mg is approved for two indications: treatment of irritable bowel syndrome with diarrhea ("IBS-D") in adults, and reduction in risk of overt hepatic encephalopathy ("HE") recurrence in adults. Counterclaims ¶¶ 43-50. The patents listed in FDA's Orange Book for Xifaxan® 550 mg tablets fall into three categories: one group directed to polymorphic forms of

rifaximin ("Polymorph Patents"), and two groups of method of use patents, one directed to each indication—the "IBS-D Patents" and the "HE Patents," respectively.[1] *Id.*

B. Hatch-Waxman Framework

The Hatch-Waxman Act, 21 U.S.C. § 355, provides a process through which manufacturers can seek FDA approval of generic versions of branded drugs via an Abbreviated New Drug Application ("ANDA"). The Hatch-Waxman process "permits a generic manufacturer to piggyback on the original manufacturer's evidence of safety and efficacy, and need demonstrate only that the generic drug has the same active ingredient(s), route of administration, dosage form, conditions of use, and strength as the approved drug, and that the generic drug has an appropriate label and is bioequivalent to the approved drug." *Norwich Pharms., Inc. v. Kennedy,* No. 25-091, 2025 WL 1148463, at *2 (D.D.C. Apr. 18, 2025) (internal citations and quotations omitted) (cleaned up).

ANDA applicants "must address patents that cover or might cover" the approved drug, which are identified by the brand manufacturer in FDA's Orange Book. *Id.* at *3 (quoting *Purepac Pharm. Co. v. Thompson,* 354 F.3d 877, 879 (D.C. Cir. 2004)). If the ANDA applicant seeks approval to market its product before a patent listed in the Orange Book expires, it must submit a Paragraph IV certification stating the patent is "invalid or will not be infringed by the manufacture, use, or sale of" its product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). "In essence, [ANDA] applicants use [P]aragraph IV certifications to challenge the validity of brand-manufacturers' patents." *Purepac,* 354 F.3d at 879. "[T]he mere act of filing a Paragraph IV ANDA constitutes an act of patent infringement." *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.,* 527 F.3d 1278, 1283 (Fed. Cir. 2008); 35 U.S.C. § 271(e)(2).

[1] The Orange Book lists nine patents directed to the HE indication. The four HE Patents raised in Counterclaim III are a subset of that group.

The Hatch-Waxman Act rewards applicants that are the first to submit an ANDA containing a Paragraph IV certification with a 180-day exclusivity period, which delays approval of subsequent ANDA applications for the same drug until that exclusivity has ended. *Norwich*, 2025 WL 1148463, at *3. The 180-day exclusivity period can also be forfeited under provisions added to the Hatch-Waxman Act by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. 21 U.S.C. § 355(j)(5)(D); *see also Norwich*, 2025 WL 1148463, at *4.

If a branded drug is approved for multiple indications, an ANDA applicant can seek approval for some or all of the FDA approved indications. If the applicant seeks approval for only some of the indications, the Hatch-Waxman Act provides a potential path to market before certain method-of-use patents expire. The applicant can design its product, including its label, to "carve out" a patented indication/method-of-use. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1327 (Fed. Cir. 2021). This allows the applicant to submit a "section viii" statement under Section 355(j)(2)(A)(viii) rather than a Paragraph IV certification to the method-of-use patents. Through a section viii statement, the applicant informs FDA "the method of use patent does not claim" a "use for which the applicant is seeking approval," 21 U.S.C. § 355(j)(2)(A)(viii), and thus, the "patent poses no bar to approval of an ANDA." *Purepac*, 354 F.3d at 880. In contrast to a Paragraph IV certification, a section viii statement does not challenge the validity or infringement of the patent. *Id.*

Here, Mylan is not a first applicant, and it submitted Paragraph IV certifications to the IBS-D and Polymorph Patents (Counterclaims ¶¶ 60-61), which constitutes an act of infringement of those patents. 35 U.S.C. § 271(e)(2)(A). [redacted] Counterclaims ¶¶

25, [redacted]

Salix asserted three patents against Mylan, one Polymorph Patent and two IBS-D Patents. Dkt. 1 ¶¶ 1, 16-19. Salix's timely lawsuit triggered a 30-month stay of approval of Mylan's ANDA, until at least August 12, 2027. Dkt. 2. Salix did not assert any HE Patents.

[redacted], Mylan now seeks declaratory judgments of non-infringement as to those patents. Counterclaims ¶ 2 and Count III. Salix seeks to dismiss Counterclaim III for lack of case or controversy.[2]

C. Prior Xifaxan® Litigations

Actavis Laboratories FL Inc., a wholly owned subsidiary of Teva Pharmaceuticals USA, Inc. (collectively, "Teva") was the first applicant to submit an ANDA for Xifaxan® 550 mg containing one or more Paragraph IV certifications. *See* Counterclaims ¶ 53; *see also Norwich*, 2025 WL 1148463, at *1. Teva earned and remains eligible for the 180-day exclusivity period granted to first applicants by 21 U.S.C. § 355(j)(5)(B)(iv); *Norwich*, 2025 WL 1148463, at *1-2. After an unsuccessful challenge by a subsequent ANDA applicant (Norwich Pharmaceuticals, Inc.), the D.C. district court recently affirmed Teva has not forfeited its 180-day exclusivity period. *Id.* at *10. Teva's licensed launch date is January 1, 2028. Counterclaims ¶ 55.

Some of the Orange Book patents for Xifaxan® 550 mg have been previously litigated. One of the HE Patents, the '573 Patent, was found valid and infringed in district court litigation involving a different generic manufacturer and ANDA. *Salix Pharms., Ltd. v. Norwich Pharms.,*

[2] Mylan also brings counterclaims of invalidity and non-infringement as to non-asserted IBS-D Patents and Polymorph Patents. Salix does not seek dismissal of these counterclaims [redacted]

Inc., No. 20-cv-430-RGA, 2022 WL 3225381, at *10, *16 (D. Del. Aug. 10, 2022). Six actions, five of which have been consolidated for discovery purposes, are pending in the New Jersey district court involving the same Orange Book patents asserted by Salix here (Case Nos. 24-cv-5607, 24-cv-7140, 24-cv-9512, 24-cv-10213, and 24-cv-10356). In those cases, Salix has not affirmatively asserted the HE Patents, and none of the defendants in those cases have brought declaratory judgment counterclaims concerning the HE Patents. The HE Patents will expire in 2029. *See* Ex. 1 (OB listing).

II. LEGAL STANDARD

Congress enacted a specific statute governing declaratory judgments in the context of patent disputes under Hatch-Waxman Act. When an application includes a Paragraph IV certification and no infringement claim has been filed within 45 days, courts have jurisdiction over an action "for a declaratory judgment that such patent is invalid or not infringed" "to the extent consistent with the Constitution." 35 U.S.C. § 271(e)(5).

In addition to the statutory requirements, Article III of the Constitution requires an actual controversy. A declaratory judgment action is justiciable where "the facts alleged, under all circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issue of a declaratory judgment." *Apotex Inc. v. Daiichi Sankyo, Inc.,* 781 F.3d 1356, 1361-62 (Fed. Cir. 2015) (quoting *MedImmune, Inc. v. Genentech, Inc.,* 549 U.S. 118, 127 (2007)).

Article III standing further requires "an injury be concrete, particularized, and actual or imminent; fairly traceable to the challenged action; and redressable by a favorable ruling." *Apotex*, 781 F.3d at 1362 (quoting *Monsanto Co. v. Geertson Seed Farms,* 561 U.S. 139, 149 (2010)). The issues presented must also be ripe for judicial review. *Caraco,* 527 F.3d at 1291 (citing *Abbott Labs. v. Gardner,* 387 U.S. 136, 149 (1967)). One element of ripeness is whether an action is "fit

for judicial review" because "further factual development would not significantly advance a court's ability" to decide the declaratory judgment action. *Caraco*, 527 F.3d at 1295 (cleaned up).

Even if an actual controversy exists, a district court is not required to exercise jurisdiction. *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.,* 482 F.3d 1330, 1338 n. 3 (Fed. Cir. 2007) (citing *Public Serv. Comm'n v. Wycoff Co.,* 344 U.S. 237, 241 (1952); *Spectronics Corp. v. H.B. Fuller Co.,* 940 F.2d 613, 634 (Fed. Cir. 1991)); *see also Centennial Life Ins. Co. v. Poston,* 88 F.3d 255, 256 (4th Cir. 1996) ("[A] declaratory judgment action is appropriate 'when the judgment will serve a useful purpose in clarifying and settling the legal relations in issue, and… when it will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding.'") (quoting *Aetna Cas. & Sur. Co. v. Quarles,* 92 F.2d 321, 325 (4th Cir. 1937)).

A Rule 12(b)(1) motion seeks dismissal because the court lacks the authority to hear the dispute. *See Holloway v. Pagan River Dockside Seafood, Inc.,* 669 F.3d 448, 452 (4th Cir. 2012). Here, Salix challenges Counterclaim III because it "simply fails to allege facts upon which subject matter jurisdiction can be based." *Adams v. Bain,* 697 F.2d 1213, 1219 (4th Cir. 1982). Accordingly, this Court must take the alleged facts as true and evaluate whether those facts are sufficient to establish subject matter jurisdiction. *Kerns v. United States,* 585 F.3d 187, 192 (4th Cir. 2009). Mylan bears the burden to demonstrate that subject matter jurisdiction over its counterclaim exists. *Lovern v. Edwards,* 190 F.3d 648, 654 (4th Cir. 1999). This Court must grant a Rule 12(b)(1) motion to dismiss "if the material jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." *Richmond, Fredericksburg, & Potomac R.R. Co. v. United States,* 945 F.2d 765, 768 (4th Cir. 1991).

A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in Counterclaim III as true and viewing them in the light most favorable to the non-moving party, a

court concludes those allegations "could not raise a claim of entitlement to relief." *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 558 (2007). A court need only accept as true the pleading's factual allegations, not its legal conclusions. *Ashcroft v. Iqbal,* 556 U.S. 662, 678 (2009); *Burnette v. Fahey,* 687 F.3d 171, 180 (4th Cir. 2012). A court must grant a motion to dismiss under Rule 12(b)(6) where a complaint fails to provide sufficient non-conclusory factual allegations to allow the court to draw the reasonable inference of the non-movant's liability. *Francis v. Giacomelli,* 588 F.3d 186, 196-97 (4th Cir. 2009).

III. ARGUMENT

Mylan invokes 28 U.S.C. §§ 2201, 2202, 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5) as the basis for this Court's jurisdiction over Counterclaim III. Counterclaims ¶¶ 1, 10-12. But the statutory language provides for jurisdiction only over declaratory judgments regarding patents that are subject to Paragraph IV certifications, and the HE Patents [redacted]. Moreover, Mylan has failed to allege an Article III case or controversy and Article III standing. Accordingly, the Court should dismiss Counterclaim III under either Rule 12(b)(1) or 12(b)(6).

A. Paragraph IV Certifications Are Required for Jurisdiction

In a sub-section titled "Civil Action to Obtain Patent Certainty," the Hatch-Waxman Act provides specific rules regarding declaratory judgments, allowing an ANDA applicant to bring a declaratory judgment counterclaim under 28 U.S.C. § 2201 for patents that are the subject of Paragraph IV certifications but were not asserted by the patent owner or NDA holder in the infringement action. 21 U.S.C. § 355(j)(5)(C); *see also Janssen Pharmaceutica, N.V. v. Apotex, Inc.,* 540 F.3d 1353, 1357 (Fed. Cir. 2008). Mylan relies on this provision as a basis for declaratory judgment jurisdiction over Counterclaim III. Counterclaims ¶¶ 12, 85.

Yet the statute makes clear jurisdiction under Section 355 (j)(5)(C) of the Hatch-Waxman Act applies **only** to a patent that is the subject of a Paragraph IV certification:

> **No action may be brought** under section 2201 of title 28 by an [ANDA] applicant… for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) **unless**—

21 U.S.C. § 355(j)(5)(C)(i)(I) (emphasis added). The "certification referred to in subparagraph (B)(iii)" is a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii). The statute requires certain prerequisites before an applicant may bring a declaratory judgment action, which are all based on submission of a Paragraph IV certification. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc). Thus, the statute provides declaratory judgment jurisdiction only for patents addressed by Paragraph IV certifications; it does not provide unfettered jurisdiction over all counterclaims concerning all Orange Book-listed patents. 21 U.S.C. § 355(j)(5)(C)(i)(II).

Mylan also relies on 35 U.S.C. § 271(e)(5) (Counterclaims ¶¶ 12, 82), which extends federal court jurisdiction over declaratory judgment actions under 21 U.S.C. § 355(j)(5)(C) to the limits of the Constitution. *See Teva v. Novartis,* 482 F.3d at 1342-43. However, 35 U.S.C. § 271(e)(5) explicitly applies only to a patent addressed by a Paragraph IV certification (and only when there has been no suit for infringement):

> Where a person has filed an [ANDA] application… that includes a [Paragraph IV] certification… and neither the owner of **the patent that is the subject of the certification** nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by **the patent** or a use of which is claimed by **the patent** brought an action for infringement of such patent… the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that **such patent** is invalid or not infringed.

35 U.S.C. § 271(e)(5) (emphasis added).

In sum, both 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5) require the applicant to have made a Paragraph IV certification to a patent for it to be the subject of a declaratory judgment.

B. [redacted] for the patents that are the subject of its declaratory judgment counterclaim. [redacted]. Counterclaims ¶ 84. Mylan accordingly represented to FDA that [redacted]. *Purepac,* 354 F.3d at 880. [redacted]. *Id.* at 879. Mylan acknowledges section viii statements and Paragraph IV certifications are mutually exclusive for addressing method of use patents listed in the Orange Book. Counterclaim ¶ 25.

[redacted], Mylan cannot invoke the Hatch-Waxman Act and the Patent Act for declaratory judgment jurisdiction over these same patents in Counterclaim III.

Mylan is correct that without a judgment on the HE Patents (as well as favorable judgments on each of the other patents qualifying Teva for exclusivity), it cannot trigger forfeiture of Teva's exclusivity. [redacted] The Hatch-Waxman Act provides a pathway for ANDA applicants to challenge Orange Book-listed patents: a Paragraph IV certification. [redacted] Mylan's attempt to now put them at issue contradicts the Hatch-Waxman Act and the Patent Act.

Section 355(j)(5)(C) and Section 271(e)(5)—which Mylan cannot satisfy—are the exclusive means for seeking a declaratory judgment in the Hatch-Waxman context. If Mylan could

seek a declaratory judgment without satisfying the requirements of Section 355(j)(5)(C) and Section 271(e)(5), then the specific requirements and limitations of those statutes would be meaningless. The only way to give effect to these provisions is to recognize these statutory routes are exclusive. Because Mylan cannot satisfy either of them, it cannot seek declaratory judgment for the HE Patents.

C. Mylan's Factual Allegations Are Insufficient to Establish an Article III Case or Controversy

Separate from the failure to satisfy statutory requirements, Counterclaim III fails to establish an Article III case or controversy concerning the HE Patents. The reason is clear: no "accused activity" exists. Salix has **not** asserted Mylan infringes the HE Patents, and Mylan [redacted]

In patent cases, a controversy sufficient to create declaratory judgment jurisdiction exists only "where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license." *Hewlett-Packard Co. v. Acceleron LLC,* 587 F.3d 1358, 1361 (Fed. Cir. 2009). "[D]eclaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee." *SanDisk Corp. v. STMicroelectronics, Inc.,* 480 F.3d 1372, 1380-81 (Fed. Cir. 2007).

Salix has not engaged in any such affirmative act. It has neither threatened suit nor accused Mylan of infringing the HE Patents through its "ongoing or planned activity." Indeed, Mylan's [redacted] deny any "arguably illegal behavior" has occurred. *See AstraZeneca Pharms. LP v. Apotex Corp.,* 669 F.3d 1370, 1379 (Fed. Cir. 2012) (The Hatch-Waxman Act "allows generic manufacturers to limit the scope of regulatory approval they seek—and thereby

forego Paragraph IV certification and a § 271(e)(2) infringement suit—by excluding patented indications from their ANDAs."). In essence, Mylan seeks an advisory action on an issue that its own [redacted] and pleadings—if accepted as true—foreclose.

Mylan alleges the *Caraco* decision supports declaratory judgment jurisdiction over any counterclaims relating to Orange Book-listed patents. *See* Counterclaims ¶¶ 89-90. But the holding and reasoning of *Caraco* are inapplicable.

First, the Federal Circuit decided *Caraco* before the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") took effect, which significantly restructured 180-day exclusivity for certain first ANDA applicants. The MMA established a single 180-day exclusivity period awarded to "first applicants" and codified certain conditions in which a first applicant could forfeit its entitlement to the 180-day exclusivity period. 21 U.S.C. §§ 355(j)(5)(B)(iv) and (j)(5)(D); *see also Teva Pharms. USA, Inc. v. Sebelius,* 595 F.3d 1303, 1306 (D.C. Cir. 2010). Thus, *Caraco* did not address whether an inability to trigger forfeiture creates a case or controversy because it was decided under the pre-MMA version of the Hatch-Waxman Act that lacked forfeiture provisions.

Second, the Federal Circuit based its analysis of standing on the facts that (i) Caraco submitted Paragraph IV certifications for both Orange Book-listed patents and (ii) the brand company chose to sue on only one, granting a covenant not-to-sue for the other. *Caraco,* 527 F.3d at 1288. However, because Caraco had submitted a Paragraph IV certification for the non-asserted patent, it needed the district court to determine whether it infringed to obtain FDA approval. *Id.* at 1288, 1297. Caraco also needed favorable judgments on both Paragraph IV-certified patents "in order to activate the [first applicant's] exclusivity period" and "obtain FDA approval as swiftly as possible." *Id.* at 1293.

Neither *Caraco* nor any decisions relying on *Caraco* have addressed the scenario here: [redacted]. Salix is aware of only one case addressing this scenario, and that case held no Article III jurisdiction exists concerning a patent addressed by a section viii statement: "[A]n ANDA applicant that submits a Section viii statement for a patent does not face the imminent threat and actual controversy of an infringement action." *In re Entresto (Sacubitril/Valsartan) Patent Litig.,* C.A. No. 20-2930-RGA, C.A. No. 21-1330-RGA, 2022 WL 4482717, at *5 (D. Del. Sept. 27, 2022) (finding no declaratory judgment jurisdiction). The *Entresto* court found no actual controversy existed because an applicant who has submitted a section viii statement has, at most, a "'subjective or speculative fear of future harm' that cannot justify subject matter jurisdiction."[3] *Id.*

Because no Article III controversy exists regarding the HE Patents, the Court should dismiss Counterclaim III.

D. Mylan Has Failed to Allege Article III Standing

The Court also should dismiss Counterclaim III because Mylan lacks Article III standing. *Teva v. Novartis*, 482 F.3d at 1337 ("A justiciable Article III controversy requires the party instituting the action to have standing"). Article III standing requires Mylan to "allege personal injury fairly traceable" to Salix's "conduct and likely to be redressed by the requested relief," with "injury-in-fact [] the most determinative." *Id.* at 1337. Mylan has failed to plausibly allege these elements.

[3] While the court found that 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5) "do not statutorily bar the declaratory judgment counterclaims," it also found that those statutes "do not… provide a statutory basis for, or subject matter jurisdiction over, Defendant's counterclaims" because they are "specific to situations where a Paragraph IV certification was filed." *Entresto,* 2022 WL 4482717, at *4.

1. Mylan has failed to allege a cognizable injury

Counterclaim III nowhere alleges Mylan has suffered or will suffer any injury or harm; it only alleges Mylan desires to "obtain final approval before [Teva's] agreed upon license date." Counterclaims ¶ 87. But this desire does not create a "cognizable Article III controversy." *Janssen,* 540 F.3d at 1361.

In *Janssen,* the Federal Circuit held a subsequent applicant's desire to trigger the first-filer's exclusivity period and thereby enter the market as soon as possible did not create a "cognizable Article III" controversy sufficient for declaratory judgment jurisdiction. The court reasoned a delay in approval due to the 180-day exclusivity period is "a result envisioned by the Hatch-Waxman Act." *Id.* at 1360-61 (explaining the Hatch-Waxman Act "struck a careful balance between encouraging the development of new drugs and enabling the marketing of low-cost generic drugs," and the 180-day exclusivity period "is an incentive" and "important" because "it promotes patent challenges" by giving a first applicant a time to "recover its investments in these challenges").

Mylan's desire to trigger forfeiture of Teva's exclusivity period is similarly insufficient. [redacted] would be due to Teva's 180-day exclusivity period, which Teva earned under the Hatch-Waxman Act. *Norwich,* 2025 WL 1148463, at *5. According to the Federal Circuit in *Janssen,* such a delay is not a cognizable injury but rather a "result envisioned by the Hatch-Waxman Act." 540 F.3d at 1361.

2. Any delay in approval would not be traceable to Salix's conduct

Even if a delay in approval due to the 180-day exclusivity period were a cognizable injury, that alleged injury must still be "fairly traceable" to Salix's conduct. *Teva v. Novartis*, 482 F.3d at 1337. Salix has done nothing here that would result in any cognizable injury to Mylan.

Counterclaim III's allegations fail to support that any delay in approval of Mylan's ANDA related to the HE Patents is traceable to Salix's conduct. [redacted]. *See Janssen,* 540 F.3d at 1361 (finding the subsequent applicant's stipulation to validity cut off the chain of causation between Janssen's actions—the listing of the patent in the Orange Book—and the alleged delay in FDA approval).

Mylan alleges Salix chose not to sue on the HE Patents to delay a "Qualifying Decision" that might trigger the failure-to-market forfeiture provision. Counterclaims ¶ 89. Not so. [redacted], **Mylan** attempted to foreclose Salix from asserting the HE Patents under Section 271(e)(2).[4] *See AstraZeneca,* 669 F.3d at 1379 ("[A] patented method of using a drug can only be infringed under §271(e)(2) by filing an ANDA that seeks approval to market the drug for that use."). Yet Mylan also alleges, despite Salix's **inaction** on the HE Patents, it is entitled to bring Counterclaim III in view of the *Caraco* decision. Counterclaims ¶¶ 89-90. Mylan's reliance on *Caraco* is unavailing.

In *Caraco,* the declaratory judgment patent was the later-to-expire patent and would continue to **independently** bar FDA approval for Paragraph IV applicants after the other Orange Book-listed patent expired. *Caraco,* 527 F.3d at 1287, n.6. The HE Patents, in contrast, will ***not***

[4] The Federal Circuit recognized in *AstraZeneca* that section viii statements do not "necessarily leave the patentee without recourse under § 271(e)(2)." 669 F.3d at 1380.

independently delay the FDA from approving Mylan's ANDA. [redacted]. *See Purepac,* 354 F.3d at 880 ("FDA may [] approve a section viii application immediately"); 21 C.F.R. § 314.107(b)(1)(ii) (ANDA may be approved "[i]mmediately, if the applicant submits an appropriate [section viii] statement"). Mylan's Paragraph IV certifications to the IBS-D and Polymorph Patents—not the HE Patents—bar FDA's approval.

If Mylan had submitted **Paragraph III** certifications to the IBS-D Patents and Polymorph Patents, its ANDA would be approvable after the last of those patents expire, in February 2029, even though the HE Patents do not expire until July 2029. [5] 21 U.S.C. § 355(j)(5)(B)(ii); Dkt. 2; Ex. 1. In this circumstance, Teva's 180-day exclusivity period would not prevent final approval of Mylan's ANDA because the exclusivity period only applies against subsequent applications that contain a Paragraph IV certification. *See* 21 U.S.C. § 355(j)(5)(B)(iv) ("[I]f the application **contains a [Paragraph IV] certification**… and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug… by any first applicant") (emphasis added); *see also Norwich,* 2025 WL 1148463, at *3.

Thus, unlike in *Caraco*, Salix's listing of the HE Patents in the Orange Book did not "create[] an independent barrier… that deprives [Mylan] of an economic opportunity to compete," 527 F.3d at 1293, because Mylan [redacted] rather than Paragraph IV certifications for those patents. Any delay in final approval of Mylan's ANDA—by the 30-month stay or Teva's 180-day exclusivity—would result from the Hatch-Waxman Act framework and

[5] A Paragraph III certification indicates the applicant is seeking approval as of the date on which the patent will expire. 21 U.S.C. § 355(j)(2)(A)(vii)(III).

Mylan's decision to make Paragraph IV certifications to **other** Orange Book-listed patents. Mylan's Paragraph IV certifications to the patents asserted by Salix in this case, not Salix's Orange Book listing of the HE Patents, will affect the timing of FDA approval. The HE Patents will have no effect on that decision.

3. A favorable judgment would not redress any alleged injury

In *Caraco,* the Federal Circuit noted favorable judgment of non-infringement would "clear the path to FDA approval" via the pre-MMA court judgment trigger of starting the 180-day exclusivity period. *Caraco,* 527 F.3d at 1293. As discussed, Mylan has failed to allege a cognizable injury, much less one traceable to Salix. Moreover, a favorable judgment on the HE Patents would not affect the final approval date of Mylan's ANDA or trigger forfeiture by Teva. Mylan is a latecomer (Teva submitted its ANDA in 2015), and Teva's exclusivity period will likely begin before Mylan could trigger its forfeiture.

First, due to the 30-month stay arising from Mylan's Paragraph IV certifications to the IBS-D and Polymorph Patents and Salix's timely filing of this action, the FDA could not approve Mylan's ANDA earlier than August 12, 2027. 21 U.S.C. § 355(j)(5)(B)(iii); Dkt. 2. A favorable judgment on the HE Patents only would not affect this date.

Second, this action is in its earliest stages. Failure-to-market forfeiture requires "a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari)" on each of the patents that qualify Teva for exclusivity, which includes IBS-D and Polymorph Patents. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb); *Norwich,* 2025 WL 1148463, at *5; Counterclaims ¶¶ 54, 56. Based on the typical timeline of patent litigation and Federal Circuit appeals, any final decision on all of the applicable patents would almost certainly issue well **after** Teva will have begun commercial marketing of its product, in January 2028. Counterclaims ¶¶ 55-56.

Mylan has not alleged, and has no basis to allege, Teva would delay launch beyond this date. Thus, unlike in *Caraco,* a judgment of non-infringement as to the HE Patents will not impact the FDA approval date. *See Caraco,* 527 F.3d at 1293. Indeed, Counterclaim III will likely become moot during the course of this action. *Cf. Dey Pharma, LP v. Sunovion Pharms. Inc.,* 677 F.3d 1158, 1166 (Fed. Cir. 2012) (allowing declaratory judgment action on non-asserted Paragraph IV patent to proceed until rendered moot).

In sum, Mylan's reliance on *Caraco* is unavailing under the circumstances here. Mylan has failed to plead an Article III controversy as to Counterclaim III, and it should be dismissed.

E. The Court Should Exercise Its Discretion and Dismiss Counterclaim III

Even if a court determines it has Article III jurisdiction, it can decline to exercise jurisdiction under the Declaratory Judgment Act. 28 U.S.C. § 2201(a). District courts have "unique and substantial discretion" in deciding whether to hear declaratory judgment actions. *MedImmune,* 549 U.S. at 136. This Court should exercise its discretion to dismiss Counterclaim III because a judgment would serve no useful purpose, seeks to bypass the structure of the Hatch-Waxman Act, and would be an inefficient use of judicial resources.

As discussed, [redacted]. Mylan argues it will need a decision on the HE Patents "in order to trigger forfeiture of Teva's 180-day exclusivity and obtain final approval for its ANDA." Counterclaims ¶ 86. However, forfeiture by Teva is not a prerequisite to final approval of Mylan's ANDA; as intended by the Hatch-Waxman Act, Teva's exclusivity period only potentially delays that final approval.

Finally, this Court should exercise its discretion to dismiss Counterclaim III as an inefficient use of judicial resources. *See In re Entresto,* 2022 WL 4482717, at *6, n. 1 ("[W]ere this Court to have subject matter jurisdiction, I would exercise my discretion not to entertain

Defendant's declaratory judgment counterclaims…. I do not believe that considering [those counterclaims] would be an efficient use of judicial resources."). As discussed, Teva's licensed launch date likely will occur before any final court decision in this ligation, which would moot the issue of triggering Teva's failure-to-market forfeiture. Moreover, adding the HE Patents to this litigation would result in the addition of an entirely different set of patents, an entirely different clinical indication, different claim construction issues, and different factual and expert issues—all when no allegation of infringement, invalidity, and/or non-infringement has been made regarding those patents.

IV. CONCLUSION

For the foregoing reasons, Salix respectfully requests this Court dismiss Counterclaim III under either Rule 12(b)(1), 12(b)(6) for lack of case or controversy, or on discretionary grounds

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EXHIBIT 1

Drug Databases (https://www.fda.gov/Drugs/InformationOnDrugs/)

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations

Home (index.cfm?resetfields=1) | Back to Product Details

Additional Information about Patents

- Patent information is published on or after the submission date as defined in 21 CFR 314.53(d)(5).
- Patent listings published prior to August 18, 2003, only identify method-of-use claims. The listed patents may include drug substance and/or drug product claims that are not indicated in the listing.
- As of December 5, 2016, an NDA holder submitting information on a patent that claims both the drug substance and the drug product (and is eligible for listing on either basis) is required only to specify that it claims either the drug substance or the drug product. Orange Book users should not rely on an Orange Book patent listing, regardless of when first published, to determine the range of patent claims that may be asserted by an NDA holder or patent owner.

Patent and Exclusivity for: N021361

Product 002
RIFAXIMIN (XIFAXAN) TABLET 550MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
002	7906542	06/01/2025	DS	DP			04/07/2011
002	7915275	02/23/2025			U-1707 U-1708		06/18/2015
002	8193196	09/02/2027	DS	DP	U-1707 U-1708		06/18/2012
002	8309569	07/18/2029			U-1707 U-1708	Y	06/18/2015
002	8518949	02/27/2026		DP			09/16/2013
002	8642573	10/02/2029			U-1481		

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
002	8741904	02/27/2026	DS		U-1526 U-1707 U-1708		07/11/2014
002	8829017	07/24/2029			U-1562		09/09/2014
002	8946252	07/24/2029			U-1481		02/03/2015
002	8969398	10/02/2029			U-1481		03/04/2015
002	9271968	02/27/2026		DP			06/08/2016
002	9421195	07/24/2029			U-1481		10/11/2016
002	9629828	07/24/2029			U-1994		04/27/2017
002	10314828	07/24/2029			U-1481		07/01/2019
002	10335397	07/24/2029			U-2579		07/24/2019
002	10456384	02/26/2029			U-2643 U-2644		11/12/2019
002	10703763	02/27/2026			U-1708 U-2847 U-2848		07/14/2020
002	10709694	07/24/2029			U-2579		07/23/2020
002	10765667	02/26/2029			U-2643 U-2644		10/19/2020
002	11564912	02/26/2029			U-3511 U-3512		02/02/2023
002	11779571	02/26/2029			U-3706		10/23/2023

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
Your search did not return any results		

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View a list of all exclusivity codes (results_exclusivity.cfm)